

REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

Response to Claim Rejections Under 35 U.S.C. §§ 102 and 103

A. Claims 7, 8, and 10-13 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Ha et al., *Calcified Tissue International*, 72:395 (2003) (reference 1).

B. Claims 7, 8, and 10-13 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Ha et al., Korean Patent Application Publication No. 1020020044745A (published June 19, 2002; reference 2).

C. Claims 7, 8, and 10-13 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Ha et al. (reference 1) in view of Spelsburg et al., *Mol. Endocrinol.* 13:819-828 (1999) (reference 3) and Suh et al., *Phytochem.* 63:209-215 (2003) (reference 4).

The rejections under 35 U.S.C. §§ 102 and 103 are respectfully traversed, for at least the following reasons.

The present claims are directed to a method of preventing or treating metabolic bone disease comprising administering a hot water extract of *Sophorae fructus* to a subject in need thereof.

In contrast, reference 1 and reference 2 both relate to a method of preventing or treating bone loss and osteoporosis by orally administering an herbal extract from *Sophorae flavescentis radix* or *Sophorae flos*.

Applicants respectfully submit that the terms "*Sophorae fructus*" of the present claims and "*Sophorae flavescentis radix*" and "*Sophorae flos*" as disclosed in the references are not scientific names, but rather are the Latin pharmaceutical names of the oriental herbs (or processed oriental herbs).

For scientific names, where organisms share the same genus name this indicates that the organisms have a taxonomic relationship with one another. However, where oriental herbs have similar Latin pharmaceutical names, this does not guarantee that the herbs are closely related. Accordingly, the fact that the Latin pharmaceutical names of the herbs

"Sophorae fructus," "Sophorae flavescens radix" and "Sophorae flos" share the term "Sophorae" does not mean that the herbs are closely related.

In fact, *Sophorae flavescens radix* is a fresh root of *Sophora flavescens* AITON, and *Sophorae flos* is a processed flower or flower bud of *Sophora japonica* L. In addition, *Sophorae fructus* is a dried ripe fruit of *Sophora japonica* L. Thus, although the three oriental herb pharmaceuticals have the term "Sophorae" in their name, the pharmaceuticals originate from different plants or different parts of same plant. In this regard, Applicants note that roots, flowers, and ripe fruits are different tissues. Thus, a person of ordinary skill in the art would expect that the contents, particularly the active ingredients, would differ one from the other.

In support of Applicants position, portions of "Pharmacopoeia of the people's republic of China, Chemical Industry Press, Beijing, China, 1997" and "Chinese herbal medicine: Materia Medica, Revised edition, Eastland Press, Seattle, Washington, 1993" are submitted herewith in the form of an Information Disclosure Statement ("Second Information Disclosure Statement"). In the references, *Sophorae fructus* and *Sophorae flos* are listed as "Fructus Sophorae" and "Flos Sophorae," respectively, because the description mode of oriental herb pharmaceuticals of China is different from that of Korea. At page 257 of the Chinese herbal medicine reference, it is disclosed that *Sophorae fructus* has a weaker effect upon bleeding than the bud (*Sophorae flos*), but is more effective in draining heat (indicated by dotted box).

In summary, although *Sophorae fructus* as recited in the present claims and *Sophorae Flos* and *Sophorae flavescens radix* as described in the references cited by the Examiner have "Sophorae" in their Latin pharmaceutical name, they refer to different oriental pharmaceuticals with differing pharmaceutical activities. Thus, neither reference 1 nor reference 2 teach each and every limitation of the present claims, and Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. § 102 rejections.

Regarding the obviousness rejection under 35 U.S.C. §103, Applicants submit that, for at least the reasons set forth above, based on the disclosure of reference 1 a person of ordinary skill in the art would not have reasonably predicted that the *Sophorae fructus* extract as recited in the present claims would have the recited activity. In addition, references 3 and 4 do not remedy the serious deficiencies of the primary reference (reference 1). Accordingly, Applicants respectfully request reconsideration and withdrawal of the § 103 rejection.

CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this Reply, or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: March 19, 2009

By:

A handwritten signature in black ink, appearing to read "Lisa E. Stahl", written over a horizontal line.

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